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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/531,851	03/20/2000	William Pendergast	36780028US04	6061

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EXAMINER

OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/531,851

Applicant(s)

PENDERGAST ET AL.

Examiner

Howard V Owens

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4,5,7</u> | 6) <input type="checkbox"/> Other:  |

### **DETAILED ACTION**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

#### **Specification**

The present status of all parent applications should be included for applications 09/199,512 and 09/122,516.

#### **Claim Objections**

Claim 13 is objected to for the use of parenthesis surrounding the compound "carbamoylmethyl" describing formula IIc.

#### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 11 is rejected under 35 U.S.C. § 102(b) as being anticipated by Gorodeski et al. (Gorodeski), American J. of Physiol., Vol. 268, C1215-26.

Claim 11 is drawn to a method of affecting the properties of the cervical and vaginal mucosa comprising administering an effective amount of a composition comprising a purinergic agent to an individual in need of treatment thereof.

Gorodeski anticipates the claim as it teaches that ATP, a purinergic agent, can acutely and reversibly modulate the paracellular permeability of cultures of human cervical cells, moreover, that ATP, when present externally on the cervix in vivo can affect the transudation or secretion of fluid from the blood into the cervicovaginal canal.

Claim Rejections 35 U.S.C. 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 11-21 are rejected under 35 U.S.C. § 103 as being unpatentable over Gorodeski et al. (Gorodeski), American J. of Physiol., Vol. 270, C1715-25.

Claim 11 is drawn to a method of affecting the properties of the cervical and vaginal mucosa comprising administering an effective amount of a composition comprising a purinergic agent to an individual in need of treatment thereof. Dependent claims 16 and 17 are drawn to administering the purinergic agent to treat vaginal dryness.

Claims 12-15, 18 and 19 are drawn to a method of affecting the properties of the cervical and vaginal mucosa comprising administering an effective amount of a composition comprising dinucleoside phosphate compounds as purinergic agents.

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Claims 20 and 21 are drawn to a method of stimulating cervical and vaginal secretions using diuridine tetraphosphate.

Gorodeski teaches that ATP, a purinergic agent, can acutely and reversibly modulate the paracellular permeability of cultures of human cervical cells, moreover, that ATP, when present externally on the cervix in vivo can affect the transudation or secretion of fluid from the blood into the cervicovaginal canal which would clearly alleviate dry conditions.

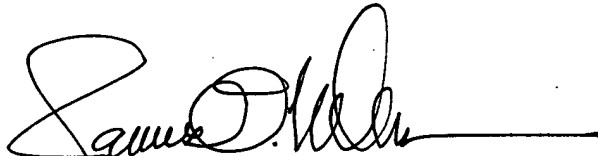
Gorodeski teaches that nucleotides which have a pyrimidine base such as UTP also affect the modulation of these fluids into the cervicovaginal canal (see C1218-C1219); however, Gorodeski does not explicitly teach the use of dinucleoside phosphates of adenosine or uridine. As the nucleotide compounds of the inventions only differ by the duplication of either the pyrimidine or purine base in the compound (or an additional phosphate in the case of diuridine tetraphosphate), in the absence of a verified showing of unexpected properties, there is no invention seen in the claimed product over the compounds of the cited prior art wherein the use of purine/pyrimidine phosphate compounds have been set forth to modulate cervicovaginal fluids. Novelty alone does not constitute invention, *In re Lincoln et al.*, 29 C.C.P.A. 942,\*; 126 F.2d 477; 53 U.S.P.Q. (BNA) 40.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use a purinergic agent to affect the properties of the cervical mucosa.

A person of ordinary skill in the art would have been motivated to use a purinergic agent to affect the properties of the cervical mucosa given that the prior art has recognized that nucleotide purinergic agents can affect the transudation or secretion of fluid from the blood into the cervicovaginal canal.

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Howard V. Owens  
Patent Examiner  
Art Unit 1623



James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.